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OFFICE OF RESEARCH INTEGRITY

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Contents

INTRODUCTION 1

SIGNIFICANT ACCOMPLISHMENTS 2
  Improve Internal Operations 2
    Case Management 2
    Case Resolution 2
    Hearings 3
    Commission on Research Integrity 3
  Improve Institutional Capabilities 3
    Institutional Compliance 3
    Model Institutional Programs 3
    Intramural Guidance 3
  Foster Research Integrity 3
    Publication Program 3
      Newsletter 3
      Biennial Report 4
      "ORI: An Introduction" 4
      Position Papers 4
      Public Notices 4

RESOLUTION OF MAJOR LEGAL ISSUES 5
  Civil Litigation 5
  Significant DAB Legal Rulings 6

SCIENTIFIC MISCONDUCT 7
  Queries 7
  Cases 7
    Institutional Inquiries 8
    Institutional Investigations 8
    ORI Inquiries 8
    ORI Investigations 8
  Summaries of Closed Investigations 8
  Investigations Resulting in Findings of Scientific Misconduct 8
  Investigations Resulting in Findings of No Misconduct 11
  Closed Investigations - Statistical Profile 12

INSTITUTIONAL COMPLIANCE ACTIVITIES 17
  Assurance Program 17
  Annual Institutional Reports 17
  Institutional Compliance Reviews 18

POLICY AND PROCEDURE DEVELOPMENT 19
  PHS Research Integrity Program 19
  Intramural Procedures for Handling Alligations 19
  Regulation on Protection of Whistleblowers 20

EDUCATION AND OUTREACH 21
  Plagiarism Conference 21
  Training Course 21
  Presentations 21
  Publications 22
  Federal Register Notices 22

OTHER ACTIVITIES 23
  PHS ALERT System 23
  Policy Studies 23
  Freedom of Information Act Requests 23
  Project Support 24

APPENDIX 25

INTRODUCTION

The Office of Research Integrity (ORI) was established in May 1992, incorporating the functions of the Office of Scientific Integrity (OSI) from the National Institutes of Health (NIH) and the Office of Scientific Integrity Review (OSIR) from the Office of the Assistant Secretary for Health (OASH). The creation of the ORI was much more than a simple consolidation of two existing offices. The ORI was established with a strong mandate to pursue and resolve allegations of misconduct in science, ensure that institutions can effectively handle allegations of misconduct, and provide education and related activities to help foster integrity in research. The ORI was placed in OASH to make it independent of funding agencies. In June 1993, Congress made ORI an independent entity within the Department of Health and Human Services (DHHS) with the Director, ORI, reporting directly to the Secretary of Health and Human Services.

The ORI oversees and directs the Public Health Service (PHS) research integrity effort, with the exception of the regulatory research activities of the Food and Drug Administration. To accomplish its mission, ORI has the following specific responsibilities:

- Assure that all institutions applying for or receiving PHS funds have appropriate mechanisms for dealing with allegations of scientific misconduct and the protection of whistleblowers; conduct reviews of institutional programs to determine whether they comply with Federal requirements; and investigate and resolve problems of institutional compliance.

- Oversee the conduct of institutional investigations of scientific misconduct allegations through the review of the reports of these investigations and the imposition of PHS administrative actions when misconduct is found.

- Conduct inquiries and investigations of scientific misconduct allegations at institutions when necessary; conduct all investigations of such allegations in PHS intramural programs.

- Develop, present, and defend findings of scientific misconduct before the Departmental Appeals Board (DAB) for those cases where a hearing has been requested.

- Develop regulations and policies to assure full and fair investigations of scientific misconduct allegations; establish appropriate due process protections for those accused of misconduct; and protect against institutional cover-up of misconduct or retaliation against whistleblowers.

- Promote research integrity through collaborative efforts with colleges and universities, scientific and professional organizations, and other Federal agencies.

SIGNIFICANT ACCOMPLISHMENTS

Nineteen ninety-three marked the first full year of ORI's existence. During this year, ORI laid out an ambitious agenda and made significant progress in accomplishing its goals. In essence, ORI developed three major long-range goals and set specific initiatives within each.

The first goal was to improve internal operations. To accomplish this goal, ORI set out to strengthen its internal management, reduce the backlog of cases, and deal with new issues as they arise. Of course, while working to improve internal operations, ORI had to carry a full load of cases (queries, inquiries, and investigations). In addition, this was the first full year of experience in the hearing process before the Departmental Appeals Board (DAB).

The second goal was to improve the capability of PHS and non-PHS institutions to deal with research misconduct issues. To this end, ORI established two sets of specific initiatives. The first was to strengthen the capability of PHS agencies to handle misconduct in intramural research; the second was to ensure that non-PHS institutions were able to fulfill their regulatory responsibilities.

The third goal was to foster research integrity programs in both PHS and non-PHS institutions. Although facing fiscal restrictions which limited its ability to provide intense technical assistance and support, ORI launched an ambitious publication program to foster and help improve research integrity efforts.

The following sections summarize specific accomplishments.

IMPROVE INTERNAL OPERATIONS

Case Management

ORI faced a set of critical management and resource issues when it was established. ORI inherited a significant backlog of cases under investigation. Exacerbating this problem was the increasing flow of queries which had to be examined to determine whether they provided the bases for misconduct cases and the opening of new, high priority cases that had to be handled within a reasonable timeframe.

To deal with these problems, ORI established a rigorous case management review and tracking system to accelerate the resolution of old cases while establishing timeframes and priorities for new issues. This system allows ORI to rationally balance current case demands while reducing the backlog of old cases. The clear results of this effort were not fully evident until 1994, when ORI accelerated greatly its resolution of cases.

Case Resolution

During 1993, while moving to improve its internal processes, ORI dealt with 196 queries, 35 of which resulted in inquiries or investigations; closed 28 cases, 10 of which resulted in a finding of misconduct; and carried 79 cases into 1994. Since it was established in May 1992, ORI has found 27 individuals to have committed scientific misconduct. ORI's findings have prevailed in 22 cases, with the remaining 5 overturned, withdrawn, or settled in conjunction with the hearing process.

Hearings

In 1993, ORI implemented the hearing process it had created in November 1992. The hearing process enables an individual against whom ORI has made a finding of scientific misconduct to request a hearing before the DAB.

Since the hearing process was established, nine individuals ORI found to have committed scientific misconduct have requested hearings. ORI prevailed in four cases; had its findings overturned in two; withdrew two; and settled one.

Commission on Research Integrity

In accordance with the mandates of the NIH Revitalization Act of 1993 (P.L. 103-43), ORI established a Commission on Research Integrity. As mandated by the law, the Commission has a broad range of responsibilities to examine the administration of the PHS research integrity effort with special emphasis on making recommendations on the definition of research misconduct. Secretary Shalala signed the charter establishing the Commission on November 4, 1993.

IMPROVE INSTITUTIONAL CAPABILITIES

Institutional Compliance

Institutions are the front line in fostering research integrity and dealing with misconduct. If institutional programs are working properly, the need for ORI to be involved directly in investigations is reduced. Therefore, ORI established a process to ensure the systematic review of institutional programs dealing with scientific misconduct. Using formal criteria, ORI analyzes an institution's policies to determine whether the policies comply with Federal regulations; then, ORI examines a case that an institution has conducted to determine if it has followed Federal regulations appropriately. The results are provided to the institution so that it can modify its policies and/or correct its procedures as necessary. ORI has begun analyzing a sample of institutions and will continue this process through 1994.

Model Institutional Programs

ORI began developing model policies and procedures for institutions to adapt to their own particular circumstances. The purpose of this effort is to provide workable examples of approaches institutions can adopt to establish an effective research integrity program. Neither formal guidance nor a set of requirements, this effort responds to the need to provide ongoing information and technical assistance to all institutions receiving PHS research funds. Begun in 1993, ORI expects to issue the first models in 1994.

Intramural Guidance

Late in 1993, ORI began work on providing the PHS agencies with specific policies and procedures on scientific misconduct in intramural research. This effort had a three-fold purpose: first, to streamline and strengthen the administrative responsibilities within the PHS for dealing with issues of scientific misconduct; second, to provide written instructions and assign responsibilities that apply when scientific misconduct is alleged or suspected in PHS programs; third, to provide information to PHS officials on procedures for assessing allegations and conducting inquiries related to possible scientific misconduct in intramural research.

This effort was completed in 1994 and training was provided to the officials from the PHS agencies at that time. Some details on this effort are found later in this report, and more detailed report of the results of this effort will be included in the 1994 Annual Report.

FOSTER RESEARCH INTEGRITY

Publication Program

The fulfillment of the ORI mission requires a collaborative effort between ORI and some 3200 institutions and organizations in the United States and 22 other countries. To facilitate that collaborative effort, ORI initiated a publication program in 1993 that resulted in the production of a quarterly newsletter, a biennial report, an informational brochure, a position paper, and public notices on misconduct findings. ORI publications are distributed free to all organizations that have submitted an assurance to the ORI and to interested individuals. The publications also are available on the Office of the Assistant Secretary for Health's Electronic Bulletin Board System. For information call (202) 690-6248. Copies of ORI publications are available from the Division of Policy and Education (DPE) at (301) 443-5300.

Newsletter

The *ORI Newsletter* is the major communication link between ORI and its constituencies. Published quarterly, the newsletter contains information about misconduct cases, the hearing process, institutional compliance reviews, regulations and procedures, advisory commission or committee meetings, protection of whistleblowers, institutional reporting requirements, legislation, congressional hearings, conferences and workshops, teaching materials, publications, awards, studies, legal issues, the promotion of research integrity, and other pertinent topics.

Biennial Report

The *ORI Biennial Report: 1991-92* was the first comprehensive report on the ORI and its predecessors. The report will be issued annually beginning with calendar year 1993.

The biennial report provided summaries of 20 closed investigations that resulted in 10 findings of misconduct and 10 findings of no misconduct. The report also contained a descriptive statistical analysis of the closed investigations. The descriptive analysis reviewed case outcome in 1991-92 by type of PHS research program, allegation, institutional action, government action, academic rank of complainant and respondent, highest degree of complainant and respondent, gender of complainant and respondent, relationship between complainant and respondent, institutional setting, funding mechanisms, length of inquiry and investigation, and size of inquiry and investigative panels.

In addition, the report contained listings of ORI conferences and workshops, project support, *Federal Register* notices, publications, and presentations.

"ORI: An Introduction"

This brochure provides an introduction to the functions, structure, and staffing of the ORI. ORI's functions include developing policies, procedures, and regulations; administering the assurance program; reviewing institutional inquiries and investigations; conducting investigations; presenting misconduct findings in hearings, and promoting research integrity.

Structurally, ORI has three components: the Office of the Director, the Division of Policy and Education (DPE) and the Division of Research Investigations (DRI). Sharing ORI quarters is the Research Integrity Branch of the Office of the General Counsel (OGC), DHHS.

The brochure also describes the ORI professional staff by type of degree, degree institution, and scientific specialization.

Position Papers

In 1993, the ORI produced its first position paper, "The Whistleblower's Conditional Privilege to Report Allegations of Scientific Misconduct." The ORI will use position papers to disseminate information on topics that require extended exposition.

The first position paper, prepared by the Research Integrity Branch, OGC, describes four circumstances in which a conditional privilege may be invoked to protect a whistleblower in a defamation suit. The paper also discusses actions by whistleblowers that may nullify their conditional privilege.

Public Notices

The ORI began issuing public notices in 1993 on closed investigations that have resulted in findings of scientific misconduct. The notices identify the respondent, the institution at which the misconduct occurred, the type of misconduct, the scientific literature involved, and the administrative actions either imposed by DHHS or agreed upon in a voluntary settlement. The notices are published in the *Federal Register*, the *NIH Guide for Grants and Contracts*, and the *ORI Newsletter*.

RESOLUTION OF MAJOR LEGAL ISSUES

Besides dealing with the newly established hearing process, ORI was confronted with a number of significant legal issues in 1993. Many of these issues have been resolved in ORI's favor through civil litigation or by the DAB in scientific misconduct appeals.

Civil Litigation

In 1993, ORI was substantially involved in four civil actions related to its scientific misconduct activities.

Two cases in 1993 and one resolved in late 1992 involved, among other issues, due process and Administrative Procedure Act (APA) challenges to ORI's procedures.

At the end of 1992, in a suit to prohibit ORI from conducting a scientific misconduct investigation, the district court granted summary judgment for the Department. Relying on the ruling in *Abbs* v. *Sullivan,* 963 F.2d 918 (7th Cir. 1992), the court held that ORI's scientific misconduct procedures were not judicially reviewable prior to the completion of the investigation and imposition of sanctions. *Terry* v. *Sullivan,* No. 91-C-0017 (E.D. Wis.).

In another case, the District Court for the Western District of Pennsylvania denied the plaintiff's request for partial summary judgment. *Hiserodt* v. *Shalala,* No. 91-0224 (W.D. Pa.). The court ruled that ORI's policies and procedures were not rules and regulations with the force of law, but rather, internal agency guidelines from which the agency in its discretion could deviate. The court dismissed the plaintiff's APA and due process claims as moot after ORI adopted a hearing process that permits *de novo* evidentiary hearings of scientific misconduct findings upon request.

In 1994, the DAB upheld ORI's finding of scientific misconduct against Dr. Hiserodt, and the district court granted the Government's motion for summary judgment, dismissing all remaining claims against ORI.

In a third case, ORI was a named defendant in a 14-count class action suit. *Needleman* v. *Healy*, No. 92-0749 (W.D. Pa.). On October 20, 1993, the district court conducted a hearing on the issue of whether one of the defendants, the University of Pittsburgh, acted as an agent for ORI. In 1994, the district court ruled that the University was not an agent of ORI and dismissed several claims against the University defendants. Other motions are pending before the court.

Another respondent and the two universities at which he conducted PHS-supported research were sued by the United States Government through a *qui tam* action for violation of the False Claims Act. The Government argued that the respondent knowingly submitted grant applications and progress reports to the

NIH that contained false statements regarding the respondent's research. *U.S. ex. rel. Condie* v. *Regents of the University of California, et al.,* No. 89-3550 (N.D. Ca.). The *qui tam* action and ORI misconduct charges were settled on terms favorable to the government in 1994.

In *McCutchen* v. *Shalala,* No. 91-142 (D.D.C.), the plaintiff filed an action under the Freedom of Information Act (FOIA) seeking access to a list of all cases closed by ORI. DHHS denied the plaintiff access to the names of respondents and complainants in cases in which there was no finding of scientific misconduct. The District Court for the District of Columbia ordered ORI to release the names of all individuals who had been accused of scientific misconduct, including those who were not found guilty. In 1994, the D.C. Circuit Court of Appeals reversed the District Court and upheld ORI's position.

Significant DAB Legal Rulings

A number of legal issues have been considered by the DAB in the course of scientific misconduct hearings in 1993. The following items represent the most important legal rulings:

- To establish scientific misconduct, ORI must demonstrate that the respondent's conduct was intentional.

- The Department's authority to take appropriate administrative actions to protect the Federal Government's interest in the integrity of federally-funded research preexisted enactment of the 1985 statute on scientific fraud and the subsequent regulation. Under this authority, ORI can prosecute scientific misconduct cases, whether intramural or extramural, in which the alleged misconduct occurred prior to promulgation of the 1989 scientific misconduct regulation.

- The PHS policies and procedures for responding to allegations of scientific misconduct adopted prior to the 1989 regulation constituted non-binding guidelines and, thus, did not require notice and comment rulemaking. As such, the policies and procedures did not violate the Administrative Procedure Act (APA).

- The authority of the PHS to prosecute scientific misconduct extends to unfunded grant applications.

- If the alleged misconduct took place prior to promulgation of the Federal scientific misconduct regulations, ORI must prove that the respondent's violation constituted a serious deviation from commonly accepted practices within the scientific community at that time.

- Respondents whose misconduct findings are overturned by the DAB may not recover attorneys' fees and expenses under the Equal Access to Justice Act (EAJA). EAJA applies only if a hearing is statutorily required; scientific misconduct hearings, by contrast, are established by agency discretion. Respondents do not have a constitutional right to scientific misconduct hearings because property interests are not at stake.

The resolution of these legal issues by the DAB and through civil litigation are important benchmarks for ORI's operations. Overall, the legal rulings have confirmed ORI's authority to prosecute scientific misconduct through the channels it has established.

The investigative workload associated with allegations of scientific misconduct includes queries and cases. Queries represent the initial contact with a potential complainant. Usually, a query contains very preliminary information, which needs to be expanded and assessed to determine whether it constitutes an allegation of scientific misconduct under PHS jurisdiction. The ORI caseload includes oversight and review of institutional inquiries and investigations and the conduct of inquiries and investigations in the PHS intramural program or at extramural institutions under special circumstances (e.g., when the institution is unable or unwilling to do the inquiry or investigation or multiple institutions are involved).

Queries

During 1993, the ORI received 196 queries, including 22 related to intramural research and 174 related to extramural research. Twenty-nine queries were referred to other Federal offices or agencies for action. Thirty-five queries resulted in inquiries and/or investigations of scientific misconduct. Institutions were requested to conduct fourteen inquiries and fourteen investigations based on the queries. The ORI began one inquiry and six investigations based on the queries. The remainder of the queries did not progress to inquiries or investigations because an evaluation by DRI concluded that the alleged behavior did not fall within the PHS definition of scientific misconduct, the research in question did not involve PHS support or a PHS grant application, or the complainant was not willing or able to provide sufficient information to make follow-up possible.

Table 1: Disposition of Queries to ORI in 1993

Queries:	196
Intramural program	22
Extramural program	174
Referred to other agencies:	29
Resulted in inquiries/investigations	35

Cases

The ORI opens a formal case only when ORI determines that the allegation involves PHS-supported research or an application for PHS support and the alleged behavior falls within the definition of scientific misconduct stated in the PHS regulation (42 C.F.R. Part 50, Subpart A)[1]. The ORI caseload is divided into four elements: (1) institutional inquiries, (2) institutional investigations, (3) ORI inquiries, and (4) ORI investigations. The ORI began 1993 with 72 cases; ORI opened

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[1] Henceforth, the term "PHS regulation" refers to 42 C.F.R. Part 50, Subpart A-Responsibility of PHS Awardee and Applicant Institutions for Dealing With and Reporting Possible Misconduct in Science.

35 new cases and closed 28 cases. Seventy-nine cases were forwarded into 1994.

Table 2: ORI Caseload by Case Type during 1993

Case Type	*Forwarded From 1992**	*Opened In 1993*	*Closed In 1993*	*Carried Into 1994*
Institutional Inquiries	20	14	12	22
Institutional Investigations	31	14	7	38
ORI Inquiries	2	1	0	3
ORI Investigations	19	6	9	16
TOTAL	72	35	28	79

* Case type totals forwarded from 1992 are slightly different than those reported in the 1991-92 Biennial Report. Inquiries and subsequent investigations (whether ORI or institutional) moved from one category to another throughout the year. These changes are reflected in this column and accurately show the current status of those cases. The total number of cases forwarded from 1991-92 increased by one because a closed investigation was returned to the open case list.

Institutional Inquiries

Under the PHS regulation, institutions are not required to report the conduct of inquiries to ORI unless they result in investigations. The ORI may become involved in institutional inquiries when ORI receives an allegation directly from the complainant and then asks the institution to conduct the inquiry; under these circumstances, the institution is required to report the outcome of the inquiry to ORI. The ORI then reviews the report to determine whether the conduct of the inquiry complied with the PHS regulation and was thorough, competent, and objective.

The ORI started the 1993 reporting period monitoring 20 institutional inquiries. The ORI referred allegations originating from queries (see above) to 14 institutions for inquiries and ORI accepted the results of 12 inquiries conducted by institutions. The ORI carried 22 institutional inquiries into 1994.

Institutional Investigations

Institutions are required by the PHS regulation to report to ORI the initiation of an investigation and to submit a report to ORI upon completion of the investigation. The ORI reviews the report to determine whether the conduct of the investigation complied with the PHS regulation and was thorough, competent, and objective. The ORI began the 1993 reporting period monitoring 31 institutional investigations. Institutions began another 14 investigations during 1993. The ORI closed seven cases involving institutional investigations and carried 38 institutional investigations into 1994. An ORI case is closed when ORI accepts an institutional finding of no misconduct, or a respondent does not request a hearing on an ORI misconduct finding, or a final finding on an ORI recommended misconduct finding is rendered by the DAB following a hearing.

ORI Inquiries

The ORI reviews all inquiries conducted into allegations of scientific misconduct within the PHS intramural research programs. In addition, ORI conducts inquiries at extramural institutions if the institution is unwilling or unable to do so. Two inquiries were underway at the beginning of the reporting period and another was opened. Three inquiries were carried into 1994.

ORI Investigations

The ORI conducts all investigations into allegations of scientific misconduct in the PHS intramural research programs. In addition, ORI conducts investigations at extramural institutions if the institution is unwilling or unable to do so or if the case involves other special circumstances. The ORI began the reporting period with 19 investigations underway. Six investigations (including two intramural) were opened during the reporting period and nine were closed. The ORI carried 16 investigations into 1994.

SUMMARIES OF CLOSED INVESTIGATIONS

Sixteen investigations were closed by ORI in 1993; nine investigations were conducted by ORI and seven were conducted by institutions. The investigations resulted in 10 findings of misconduct and six findings of no misconduct. Summaries of these cases are presented below in two sections: (1) investigations resulting in findings of scientific misconduct, and (2) investigations resulting in findings of no misconduct.

INVESTIGATIONS RESULTING IN FINDINGS OF SCIENTIFIC MISCONDUCT

Fabrication:

Fumihiko Sugata, M.D., National Institute of Allergy and Infectious Diseases (NIAID), NIH. An inquiry conducted by NIAID and a subsequent investigation conducted by ORI found that Dr. Sugata, a Fogarty Visiting Scientist in the Laboratory of Infectious Diseases at the NIAID, had fabricated data in molecular biological research on the hepatitis virus. The inquiry and investigation found that there was no scintillation counter printout to support quantitative scintillation count data for one experiment recorded in Dr. Sugata's notebook. Dr. Sugata admitted that he had constructed the data from rough estimates based on autoradiograms, rather than from an actual scintillation counter run. He explained that he was under pressure from his professor in Japan to publish scientific papers, and that when he ran out of scintillation fluid he did not want to delay his project for the two or three weeks necessary to replenish the stock of fluid. ORI concluded that the fabrication of data constituted scientific misconduct. Dr. Sugata has signed an agreement with the ORI that he will exclude himself for a two-year period beginning September 1, 1993, from any Federal grants or contracts, and from serving on any Public Health Service advisory committees for a three-year period beginning on that date. Dr. Sugata also agreed that any applications for PHS support that he submits from September 1, 1995, to August 31, 1996, will be certified as to accuracy and reliability. The fabricated data did not appear in any scientific publications.

Torrey Johnson, Tufts University. An inquiry and a subsequent investigation conducted by the university found that Mr. Johnson, a predoctoral graduate student in the Department of Biology, had fabricated research data on the genetic control of spermatogenesis. Mr. Johnson worked on a grant from the National Institute of Child Health and Human Development. The university investigation concluded that Mr. Johnson fabricated reports that he had extracted, purified, and characterized a transcription factor protein. Mr. Johnson's notebooks provided no details on the purification procedures and he was unable to describe to his thesis committee the steps used to purify the protein. The investigation also concluded that it was likely that Mr. Johnson had used commercially-obtained human transcription factor instead of the claimed purified protein from mouse testis. ORI concurred in the university's findings, and Mr. Johnson has been debarred from receiving Federal grant or contract funds for a three-year period beginning May 14, 1993. For two years beyond the debarment period, any research institution which employs Mr. Johnson must provide the PHS a plan for the oversight of his scientific activities and certify the accuracy and integrity of information provided in PHS applications or in reports generated under a PHS award. Two abstracts containing fabricated data were withdrawn ("Footprint analysis of the promoters of mouse and rat protamine 2 genes reveals differences in protein binding" presented at the XIth North American Testis Workshop, and "Protein binding to a conserved promoter element of the male germ cell specific mouse protamine 1 and 2 genes suppresses transcription in vitro in non-expressing tissues" *J. Cell Biology Abstracts*, **115**: 48a, 1991).

Falsification:

Mitchell H. Rosner, National Cancer Institute. An inquiry conducted by the National Cancer Institute (NCI) and a subsequent investigation conducted by ORI found that Mr. Rosner, a Howard Hughes Medical Institute-NIH scholar in residence at the NCI, falsified research on embryonic development in mice. Mr. Rosner diluted control samples that were injected into mouse germ cells so that the control material would have a different effect on embryonic development from the experimental samples. The results of these experiments were published in the journal *Cell*, demonstrating that a certain regulatory protein was essential for normal embryonic development. In later efforts by Mr. Rosner's collaborators and supervisors to replicate the original findings, Mr. Rosner again diluted control samples before their injection into mouse germ cells in order to obtain the previous results. Mr. Rosner admitted to these acts of falsification, and has signed an agreement with ORI that he will exclude himself for a five-year period beginning April 1, 1992, from any Federal grants or contracts, and from serving on PHS advisory committees. The publication containing the falsified results (*Cell*, **64**: 1103-1110, 1991) has been retracted by a notice in *Cell*, **69**: 724, 1992.

Raphael B. Stricker, M.D., University of California at San Francisco. An investigation conducted by the university found that Dr. Stricker falsified data for a manuscript and a PHS-supported publication reporting research on AIDS. In the manuscript, Dr. Stricker selectively suppressed data that did not support his hypothesis, and reported consistently positive data whereas only one of four experiments had produced positive results. In the publication, Dr. Stricker reported that an antibody was found in 29 of 30 homosexuals, but not found in non-homosexuals. However, Dr. Stricker's control data, which he suppressed, showed the antibody in 33 of 65 non-homosexuals. The falsified data were used as the basis for a grant application to the NIH. ORI concurred in the university's finding. Dr. Stricker executed a Voluntary Exclusion and Settlement Agreement in which he has agreed not to apply for Federal grant or contract funds and will not serve on PHS advisory committees, boards or peer review groups for a three-year period beginning April 1, 1993. The publication "Target platelet antigen in homosexual men with immune thrombocytopenia" in the *New England Journal of Medicine*, **313**: 1315-1380, 1985, has been retracted (*New England Journal of Medicine*, **325**: 1487, 1991).

Raymond J. Ivatt, Ph.D., Cetus Corporation, Emeryville, CA. An investigation conducted by the corporation found that Dr. Ivatt falsified progress reports in a research project grant supported by the NIH. Dr. Ivatt reported progress from an earlier budget period, claiming that the work had been done during the period for which current funds were awarded. The

ORI concurred with the Corporation's findings and has required that applications for PHS research support and reports of PHS-sponsored research involving Dr. Ivatt be reviewed and certified by the sponsoring institution for the reliability and accuracy of the application, contract proposal, or report. Dr. Ivatt is also prohibited from serving on PHS Advisory Committees, boards, or peer review groups. These actions are effective for 3 years beginning February 28, 1993.

Fabrication/Falsification:

Paul F. Langlois, D.Sc.N., Laboratory of Clinical Investigation, NIAID. An inquiry by the NIAID and a subsequent investigation conducted by the former OSI at the NIH concluded that Dr. Langlois, a former post-doctoral fellow in the laboratory, had falsified and fabricated data in immunological research. Dr. Langlois presented computer printouts and graphs to his supervisor for which primary data did not exist. Dr. Langlois admitted to fabricating the data. Dr. Langlois also admitted to manipulating the reagents used by other laboratory personnel in efforts to replicate his findings, spiking them with radioactive antibody to show positive results. The PHS recommended that Dr. Langlois be debarred from receiving Federal grant or contract funds for a three-year period, and that he be prohibited from serving on PHS advisory committees, boards, or peer review groups for three years. Dr. Langlois appealed the term of the proposed debarment to the DAB which upheld the PHS recommendation. Accordingly, Dr. Langlois has been debarred for three years beginning May 12, 1993, and is prohibited from serving on PHS advisory committees, boards, or peer review groups for the same period. The fabricated and falsified data was never published in the scientific literature.

Tian-Shing Lee, M.D., Joslin Diabetes Center, Harvard Medical School. An investigation conducted by Harvard found that Dr. Lee, a former post-doctoral fellow at the Joslin Diabetes Center, fabricated and falsified data in diabetes research supported by the National Eye Institute. Primary data was missing for almost half of the figures and tables in a series of published papers and manuscripts prepared by Dr. Lee. Many instances of data fabrication and falsification were found, including presenting data for cell counts that were never performed, indicating that multiple data points were determined when in fact only a single data point was obtained, eliminating the highest or lowest values in sets of experimental readings, alteration or transposition of data to achieve a desired experimental result, and misrepresentation of the time intervals at which data were collected. ORI concurred with the university's findings. Dr. Lee has been debarred from receiving Federal grants or contracts and is prohibited from serving on PHS advisory committees, boards, or peer review groups for a five-year period beginning April 18, 1993. Harvard University notified the four scientific journals which had published papers containing data fabricated or falsified by Dr. Lee that the papers should be retracted. These papers are: "Differential regulation of protein kinase C and (Na,K)-adenosine triphosphatase activities by elevated glucose level in retinal capillary endothelial cell" *Journal of Clinical Investigation*, **83**: 90-94, 1989; "Endothelin stimulates a sustained 1,2-diacylglycerol increase and protein kinase C activation in bovine aortic smooth muscle cells" *Biochemical and Biophysical Research Communications*, **162**: 381-386, 1989: "Activation of protein kinase C by elevation of glucose concentration: Proposal for a mechanism in the development of diabetic vascular complications" *Proceedings of the National Academy of Sciences*, **86**: 5141-5145, 1989; and "Characterization of endothelin receptors and effects of endothelin on diacylglycerol and protein kinase C in retinal capillary pericytes" *Diabetes*, **38**: 1642-1646, 1989.

Roger Poisson, M.D., St. Luc Hospital, Montreal, Canada. An investigation conducted by ORI found that Dr. Poisson had fabricated and falsified research data in clinical trials on breast cancer treatment supported by a cooperative agreement from the NIH. Dr. Poisson fabricated or falsified data related to laboratory tests and dates of procedures in 115 separate instances dating from 1977 through 1990. Dr. Poisson is prohibited from serving on PHS advisory committees, boards, or review groups for an eight-year period. Dr. Poisson has also been debarred from receiving Federal grants or contracts for an eight-year period. These actions became effective March 30, 1993. The National Cancer Institute cooperative clinical trials group which sponsored the clinical trials, the National Surgical Adjuvant Breast and Bowel Project (NSABP), plans to publish corrected analyses of affected studies.

Judy Guffee, University of Miami. An investigation conducted by the university found that Ms. Guffee had fabricated data in a research project that was supported by a grant from the NIH. Ms. Guffee admitted to falsifying the labeling of solutions alleged to contain polyclonal antiserum, when in fact she filled the tubes with fetal calf serum. The investigation concluded that this was done to hide the fact that the animal used to generate the polyclonal antiserum had died before large quantities of antiserum could be produced. Records indicating collection of large quantities of serum from the animal over a two-year period were also fabricated. ORI concurred in the university's finding and has required, for a five-year period beginning January 7, 1993, that she and the institution submit a certification with any PHS fellowship or grant application or contract proposal prepared by her attesting to the accuracy of the statements therein.

Fabrication/Plagiarism/Other:

James H. Freisheim, Ph.D., Medical College of Ohio. An inquiry and an investigation conducted by the university found that Dr. Freisheim had submitted a research grant application to the NIH which contained substantial portions plagiarized from another scientist's grant application. Dr. Freisheim had served as an assigned reviewer of the other scientist's application when it was reviewed about two years earlier by an NIH study section. During the inquiry, Dr. Freisheim produced a handwritten draft of the plagiarized material that he claimed he had written before the other scientist had submitted his grant application, and that therefore the other scientist had plagiarized Dr. Freisheim's work. The investigation reviewed the handwritten draft and concluded that it had been written much later than purported by Dr. Freisheim, possibly during the inquiry to establish the basis for his defense. The investigation also concluded that Dr. Freisheim had plagiarized material for two post-doctoral fellowship applications to the NIH. The ORI concurred with the university's findings, and Dr. Freisheim has been debarred from receiving Federal grant or contract funds for a period of three years beginning May 5, 1993. He has also been required, for a ten-year period beginning May 5, 1993, to certify that future applications for research support submitted to the PHS are his own work, and he has been prohibited from serving on PHS advisory committees or review groups for the same period.

INVESTIGATIONS RESULTING IN FINDINGS OF NO MISCONDUCT

Falsification: The OSI conducted an inquiry into questions raised in a newspaper article about the work done by two NIH intramural researchers on a virus. (The following summary describes the allegation against the second researcher.) The inquiry recommended that an investigation be conducted into the research reported in an article on which the first respondent was the first author. The OSI investigation concluded that the article falsely described the methodology of the study and misrepresented or falsified data presented in two tables. However, the misrepresentations did not invalidate the reported findings. The misconduct findings were confirmed by an ORI review team. The respondent asserted that the misrepresentations were the result of misunderstandings or error. The ORI recommended that for a three-year period any institution at which the respondent participated in PHS-supported research had to submit to the funding agency a plan for his close supervision. The respondent appealed the ORI findings. The DAB overturned the ORI findings, ruling that ORI did not prove misconduct by a preponderance of the evidence. The DAB concluded that the allegedly false statements were open to interpretations other than those attributed to them by the ORI.

Falsification: The OSI conducted an inquiry into questions raised in a newspaper article about the work done by two NIH intramural researchers on a virus. (The above summary described the allegations against the first researcher.) The OSI inquiry found insufficient evidence for allegations against the second researcher, including possible misappropriation of a virus discovered by another laboratory. However, the ORI review concluded that a statement written by the researcher, claiming that the virus the NIH researcher received from another laboratory had not been transmitted to a permanently-growing cell line, was false. ORI concluded that the NIH lab records showed that the virus had been transmitted to a permanently-growing cell line. The respondent asserted that the virus was only temporarily transmitted to a permanent cell line in his lab. He also claimed that the disputed statement referred to the ability of the other lab to transmit the virus to a permanent cell line. The ORI recommended that NIH submit to the Assistant Secretary for Health a plan to ensure the accurate recording and reporting of research conducted in the respondent's laboratory for a three-year period and require any extramural institution through which the respondent might apply for PHS funds to submit a plan for supervising his research for a three-year period. The respondent appealed the ORI findings and recommended actions to the DAB. Given the decision in the case cited above, the ORI withdrew its findings against the second researcher.

Fabrication/Falsification: Allegations of data fabrication/falsification were raised in a community oncology program when it was learned that two patients had died prior to the date of progress notes entered in the record. The ORI conducted an inquiry and subsequent investigation of the allegations because of the small size of the institution involved. The respondent claimed she received the recorded information from an oncologist's medical assistant and from a male she talked to when she called the patient's home. The medical assistant denied providing the information and the investigation concluded that the respondent may have mistakenly talked to the brother of the deceased patient. The investigation further determined that numerous other data discrepancies existed in the research records. These were attributed to poor training, inadequate record-keeping, carelessness, and/or honest error. Previous audits of the institution confirmed a pattern of poorly kept hospital patient records.

Fabrication/Falsification: Several allegations of scientific misconduct were made against a professor by two members of her laboratory. An inquiry conducted by the institution concluded that an investigation was not warranted. On reviewing the university report, the OSI determined that several issues required further exploration and opened its own investigation. The OSI investigation concluded that the respondent falsely reported the use of an animal model in her laboratory to support the research she was proposing in a grant application. The ORI accepted the OSI finding and recommended that the respondent be prohibited from serving on a PHS advisory committee for three years and that the applicant institution be required to certify the accuracy and reliability of applications in which the respondent participates for the same period. The respondent appealed the ORI finding and recommended actions. Prior to the hearing, the ORI agreed to withdraw its prosecution and the respondent agreed to drop the appeal.

Fabrication/Falsification: A section head at a medical institution was accused by two members of his section of making false statements in three grant applications submitted to the NIH. Two inquiries and an investigation were held by the institution. The first inquiry found no evidence of intentional misrepresentation and concluded that the misstatements were due to anticipatory writing and carelessness. After being informed that his contract would not be renewed, the respondent asserted that he was not afforded appropriate due process in the evaluation of his professional performance. The institution decided to conduct a second inquiry which concluded that an investigation was warranted, but the investigation found no misconduct. Upon review of the institutional report, OSI decided to launch its own investigation. However, the investigation was transferred to OSIR (because of the prior involvement of a senior NIH official) and eventually to ORI. The OSIR investigation concluded that false statements appeared in three applications. The statements reported the use of a probe based on sequence data of a unique receptor, sequence data on a protein, and the production of antibodies. The respondent admitted that the sequence data and antibodies did not exist, and he variously attributed the false statements to anticipated acquisition of the sequence data, editing or typographical errors, carelessness, and misrepresentations by one of the complainants. The ORI concluded that the respondent committed scientific misconduct by claiming he had used a probe based on sequence data on the receptor in one application and by claiming that he had sequence data on the protein in another application. The ORI recommended that the respondent be prohibited from serving on PHS advisory committees for three years and that the applicant institution certify that any application submitted by the respondent be reviewed by another researcher before submission. The respondent appealed the finding and the recommended actions. In overruling the ORI findings, the DAB concluded that "ORI did not prove that negligent inclusion of a false statement in a grant application in the circumstances involved in this case would so seriously deviate from accepted practice at the time as to constitute scientific misconduct. Thus, ORI could establish scientific misconduct in this case only if it proved by a preponderance of the evidence that (the respondent) intentionally falsified material statements in his grant application."

Plagiarism/Other: Several allegations were made by an associate professor against the department chairman with whom he had been doing collaborative research. An investigation conducted by the institution found no misconduct. Upon review, ORI concluded that the following allegations did not fall under the PHS definition of scientific misconduct: (1) failure to inform a collaborator that another researcher was recruited into the project; (2) exercising legitimate authority in limiting access to equipment and facilities; and (3) assignment of authorship credit. The ORI further concluded that the evidence did not support an allegation of plagiarism because the published work gave sufficient credit to the complainant and other authors.

CLOSED INVESTIGATIONS - Statistical Profile

This section presents a descriptive analysis of the 16 investigations closed during 1993 under 10 headings: (1) Setting of Closed Investigations, (2) Allegations, (3) Institutional Actions, (4) Government Actions, (5) Respondent, (6) Relationship between Complainant and Respondent, (7) Complainant, (8) Length of Inquiries, (9) Length of Investigations, and (10) Size of Panels. Investigative outcomes are based on the final disposition of the case including the result of any hearing.

Setting of Closed Investigations

The setting of closed investigation is described from four perspectives: (1) the supporting PHS research program, (2) the institutional setting, (3) the funding mechanism, and (4) the performer of the investigation.

PHS Research Program

Eleven investigations closed in 1993 involved the extramural research programs; 5 investigations involved the intramural programs. The extramural investigations occurred at 11 institutions. The five intramural investigations took place in two institutes of the NIH. Ten of the 16 closed investigations (62 percent) resulted in findings of misconduct.

Table 3: Outcome of Investigations by PHS Research Program, 1993

Program	*Misconduct*	*No Misconduct*	*Total*
Extramural	7	4	11
Intramural	3	2	5
TOTAL	10	6	16

Institutional Setting

Besides medical schools, investigations were conducted at medical centers, a biotechnology corporation, a community oncology program, and a hospital. Within extramural institutions, the investigations involved a variety of departments including laboratory medicine, brain and vascular research, immunology, microbiology and molecular biology, molecular physiology and biophysics, and biology. Within intramural programs, the investigations involved laboratories of tumor cell biology, clinical investigation, and infectious disease.

Table 4: Outcome of Investigations by Institutional Setting, 1993

Setting	*Misconduct*	*No Misconduct*	*Total*
Medical School	5	2	7
Intramural	3	2	5
Other	2	2	4
TOTAL	10	6	16

Funding Mechanism

Four funding mechanisms were involved in the 16 investigations closed in 1993. The extramural cases involved the RO1, the traditional investigator-initiated grant and two types of cooperative agreements: the UO1 - a research project, and the U10 - cooperative clinical research. Government support occurred either through the RO1 or through intramural funding in all except two of the investigations.

Table 5: Outcome of Investigations by Funding Mechanism, 1993

Funding Mechanism	*Misconduct*	*No Misconduct*	*Total*
RO1	6	3	9
UO1	0	1	1
U10	1	0	1
Intramural	3	2	5
TOTAL	10	6	16

Performer of Investigation

Institutions conducted seven of the 11 extramural investigations. ORI took responsibility for the investigation in four extramural cases. Institutions found misconduct in six of seven investigations. ORI found misconduct in eight of nine investigations. However, two ORI misconduct findings were overturned by the DAB and ORI withdrew two other misconduct findings during the hearing process.

Table 6: Outcome of Investigations by Performer of Investigation, 1993

Performer	*Misconduct*	*No Misconduct*	*Total*
Institutional	6	1	7
ORI	4	5	9
TOTAL	10	6	16

Allegations

Allegations of fabrication and/or falsification provided the basis for 15 of the 16 investigations (94 percent). Allegations of plagiarism or "other practices" occurred in two investigations. Falsification was involved in 12 investigations; seven in combination with fabrication and five as a solo allegation, making falsification the most frequent allegation occurring in these investigations. Fabrication was involved in 10 investigations; seven in combination with falsification, once as a solo allegation; once in combination with plagiarism and other practices. No investigation was based solely on an allegation of "other practices." Nine investigations were based on multiple allegations; seven were based on solo allegations.

Table 7: Outcome of Investigations by Type of Allegation, 1993

Allegation	*Misconduct*	*No Misconduct*	*Total*
Fabrication	2	0	2
Falsification	3	2	5
Fab/Falsification	4	3	7
Fab/Plag/Other	1	0	1
Plagiarism/Other	0	1	1
TOTAL	10	6	16

Institutional Actions

The PHS regulation on misconduct in science requires institutions to impose appropriate sanctions on individuals when the allegation of misconduct has been substantiated. Institutions took nine actions against respondents in six cases which resulted in findings of misconduct and in one case that did not. The most frequent action taken resulted in separating the respondent from the institution either through resignation or termination. In one case a research fellow was required to repay his fellowship funds to the university. In the case where no misconduct was found, a letter of reprimand was issued for egregious errors and failure to have grant proposals reviewed by co-investigators prior to submission.

Table 8: Outcome of Investigations by Institutional Action, 1993

Institutional Action	*Misconduct*	*No Misconduct*	*Total*
Letter of Reprimand	1	1	2
Accepted resignation	4	0	4
Terminated employment	2	0	2
Repayment of Funds	1	0	1
TOTAL	8	1	9

Government Actions

The PHS regulation on misconduct in science also recognizes the authority of the Department to impose actions of its own on investigators and institutions for violating the regulation. The Department and the PHS took 21 administrative actions against respondents in the 10 misconduct cases. Multiple actions were taken against respondents in nine of the 10 misconduct cases. Debarment was the most frequently imposed administrative action. The DHHS debarred eight of 10 respondents for periods ranging from two to eight years. In eight cases, the respondent also was prohibited from serving on PHS advisory committees, boards and initial review groups for periods ranging from three to 10 years. Integrity certifications were imposed in five cases to ensure proper attribution of sources or authenticity of data for periods ranging from one to 10 years.

Table 9: Frequency of Type of Government Action, 1993

Government Actions	*Frequency*
Debarment	8
Advisory Committee	8
Certification	5
TOTAL	21

Respondents' Academic Rank

Respondents in the 16 investigations that were closed in 1993 ranged from technician to professor. The respondents were equally divided among senior (professor and associate professor) and junior personnel (fellow, graduate student, technician). Senior personnel comprised 40 percent of the respondents found to have committed scientific misconduct; junior personnel comprised 60 percent.

Table 10: Outcome of Investigations by Academic Rank of Respondent, 1993

Respondent	*Misconduct*	*No Misconduct*	*Total*
Professor	2	0	2
Assoc. Prof.	2	4	6
Fellow	3	1	4
Grad Student	2	0	2
Technician	1	1	2
TOTAL	10	6	16

Respondents' Highest Academic Degree

Seventy-five percent of the accused respondents held a doctorate; 44 percent held an M.D. degree, and 31 percent held a Ph.D. degree. The remaining respondents had a bachelor's degree or less. Seventy percent of the respondents found guilty of scientific misconduct held doctorates; 40 percent held an M.D. degree, and 30 percent held a Ph.D. degree.

Table 11: Outcome of Investigations by Highest Academic Degree of Respondent, 1993

Degree	*Misconduct*	*No Misconduct*	*Total*
Ph.D.	3	2	5
M.D.	4	3	7
B.S.	2	0	2
B.A.	1	0	1
R.N.	0	1	1
TOTAL	10	6	16

Respondents' Gender

Eighty-one percent of the accused respondents were male; 90 percent of the respondents found guilty of scientific misconduct were male. Sixty-nine percent of the investigations of male respondents found scientific misconduct; thirty-three percent of the investigations of female respondents found scientific misconduct.

Table 12: Outcome of Investigations by Gender of Respondent, 1993

Respondent	*Misconduct*	*No Misconduct*	*Total*
Male	9	4	13
Female	1	2	3
TOTAL	10	6	16

Complainants' Relationship to Respondents

The relationships that existed between complainants and respondents in the 1993 closed investigations were diverse. The most frequent relationship was supervisory - department chair, lab chief, supervisor - and those allegations were supported in seven of eight cases. Other relationships include colleague and reviewer. In two cases, the complainant was a reporter who had no relationship to the respondents.

Table 13: Outcome of Investigations by Relationship of Complainant to Respondent, 1993

Complainant	*Misconduct*	*No Misconduct*	*Total*
Department Chair	2	0	2
Lab Chief	4	0	4
Supervisor	1	1	2
Colleague	1	2	3
Reviewer	0	1	1
Other	0	2	2
Unknown	2	0	2
TOTAL	10	6	16

Complainants' Academic Rank

The complainants spanned the academic rank structure. Seven complainants were senior personnel (professor and associate professor, 44 percent); five complainants were junior personnel (31 percent), and the academic rank of four complainants was not determined (25 percent).

Table 14: Outcome of Investigations by Academic Rank of Complainant, 1993

Rank	*Misconduct*	*No Misconduct*	*Total*
Professor*	5	1	6
Assoc. Professor	0	1	1
Research Assoc.	0	1	1
Fellow	3	0	3
Lab Technician	0	1	1
Unknown	2	2	4
TOTAL	10	6	16

*Includes a senior director of a corporate laboratory.

Complainants' Highest Academic Degree

The majority of complainants held doctorates. Seven complainants (44 percent) held Ph.D.s, five held M.D.s (31 percent), and the academic degree of the remaining four complainants (25 percent) was not determined.

Table 15: Outcome of Investigations by Highest Academic Degree of Complainant, 1993

Degree	*Misconduct*	*No Misconduct*	*Total*
Ph.D.	4	3	7
M.D.	4	1	5
Unknown	2	2	4
TOTAL	10	6	16

Complainants' Gender

The complainants were mostly males. Eleven complainants were males (69 percent) and three were females (19 percent). The gender of the remaining two complainants was not determined (12 percent).

Table 16: Outcome of Investigations by Gender of Complainant, 1993

Gender	*Misconduct*	*No Misconduct*	*Total*
Male	6	5	11
Female	2	1	3
Unknown	2	0	2
TOTAL	10	6	16

Length of Inquiry

According to the PHS regulation, institutions are required to complete an inquiry "within 60 calendar days of its initiation unless circumstances clearly warrant a longer period". When a longer period is required, the circumstances warranting the longer period must be included in the inquiry report. However, the regulation does not stipulate the starting and ending points of an inquiry. In Table 17, the 60-day period was measured from the date on which the inquiry panel held its first meeting to the date of the inquiry panel report. Using this criteria, seven inquiries (44 percent) were completed within the 60-day period stipulated in the regulation. The length of inquiries ranged from three days to 110 days.

Table 17: Outcome of Investigations by Length of Inquiry, 1993

Inquiry Length	*Misconduct*	*No Misconduct*	*Total*
0-60 days	5	2	7
61-90 days	2	0	2
91-120 days	2	4	6
Unknown*	1	0	1
TOTAL	10	6	16

*The inquiry report did not contain the date of the first meeting of the inquiry committee.

Length of Investigations

According to the PHS regulation, "an investigation should ordinarily be completed within 120 days of its initiation. This includes conducting the investigation, preparing the report of findings, making that report available for comment by the subjects of the investigation" and submitting the report to the ORI. If additional time is needed, the institution is required to request an extension from ORI. However, the regulation does not stipulate a starting point for investigations. In Table 18, the length of the investigation was measured from the date of the first meeting of the investigation committee to the date ORI received the report. Five investigations (31 percent) were finished within 120 days; nine investigations (56 percent) were completed in more than 120 days, and the length of two investigations (13 percent) could not be determined. The length of investigations, ranged from five days to 1032 days. The longest effort included both a university and an ORI investigation.

Table 18: Outcome of Investigations by Length of Investigation, 1993

Length	*Misconduct*	*No Misconduct*	*Total*
0-120 days	4	1	5
121-180 days	1	0	1
181-240 days	1	0	1
Over 300 days	4	3	7
Unknown*	0	2	2
TOTAL	10	6	16

*The investigation report did not contain the date of the first meeting of the investigation committee.

Size of Panels

The PHS regulation requires institutions to secure "necessary and appropriate expertise to carry out a thorough and authoritative evaluation of the relevant evidence in any inquiry or investigation." In conducting inquiries, institutions established panels ranging between one to eight members to provide this expertise. The modal size of inquiry panels was one member; the median panel size was three members.

Table 19: Outcome of Investigations by Size of Inquiry Panel, 1993

Members	*Misconduct*	*No Misconduct*	*Total*
One	5	0	5
Two	0	1	1
Three	3	0	3
Four	1	3	4
Five	0	0	0
Six	1	1	2
Eight	0	1	1
TOTAL	10	6	16

The size of the investigative panels also ranged from one to eight members. The size of the investigative panels was bi-modal - three and five; the median size was four and a half members.

Table 20: Outcome of Investigations by Size of the Investigative Panel, 1993

Members	*Misconduct*	*No Misconduct*	*Total*
One	1	0	1
Three	3	1	4
Four	3	0	3
Five	1	3	4
Six	0	2	2
Seven	1	0	1
Eight	1	0	1
TOTAL	10	6	16

INSTITUTIONAL COMPLIANCE ACTIVITIES

The PHS regulation on misconduct in science places several requirements on institutions receiving funds under the PHS Act. ORI monitors institutional compliance with these requirements through the following activities: (1) Assurance Program, (2) Annual Institutional Reports on Possible Misconduct in Science, and (3) Institutional Compliance Reviews.

Assurance Program

To be eligible for PHS research funding, each institution that applies for or receives a grant, fellowship, or cooperative agreement must file an institutional assurance (PHS form #6315) with the ORI that makes two declarations:

(1) The institution has an administrative process for handling allegations of scientific misconduct that complies with the PHS regulation.
(2) The institution will follow its administrative process and the regulatory requirements when responding to allegations of misconduct in science.

As of December 31, 1993, there were 3,232 active assurances on file in ORI, including 175 assurances from institutions in 22 foreign countries.

Annual Institutional Reports

In addition to filing an assurance, each institution with an active assurance is required to submit to the ORI an Annual Report on Possible Misconduct in Science (PHS form #6349) that provides aggregate information on allegations, inquiries, investigations and other activities required by the PHS regulation. If the institution does not submit the required annual report, the institutional assurance lapses, and the institution is not eligible to apply for or receive PHS research funds.

Seventy-two institutions had activities related to allegations of scientific misconduct during the two-year period 1991-1992, according to their Annual Reports. Thirty-five institutions reported such activity in 1991; 55 institutions reported such activity in 1992, and eighteen institutions reported activity in both years.

The activities reported provide the ORI with an indication of the numbers and types of scientific misconduct allegations occurring. Reportable activities are limited to allegations and the conduct of inquiries and/or investigations related to research, research training, or other research-related activities supported by the Public Health Service.

Fifty-five institutions received 108 allegations during 1991-92. The number of allegations received by the institutions ranged from 1 to 10. The median number of allegations received was

1. Thirty-one institutions received one allegation; 13 received two; five received three; two received four; and one institution received five, six, seven, and 10 allegations, respectively.

The 108 allegations contained 150 charges of scientific misconduct: 25 of fabrication, 41 of falsification, 38 of plagiarism, and 46 of "other practices."

Sixty-five institutions conducted 121 inquiries in 1991-92. Some of the inquiries were based on allegations made prior to 1991. The number of inquiries conducted by the institutions ranged from one to 11. The median number of inquiries conducted was one. Thirty-nine institutions conducted one inquiry, 14 conducted two, seven conducted three, and one institution conducted four, five, six, seven, and 11 inquiries, respectively.

Thirty-three institutions conducted 51 investigations in 1991-92. The number of investigations ranged from one to four. The median number of investigations conducted was one. Twenty institutions conducted one investigation, nine conducted two, three conducted three, and one conducted four.

Institutional Compliance Reviews

In 1993, ORI added formal institutional compliance reviews to its oversight of extramural inquiries and investigations. This function, previously handled informally by the DRI within ORI, has been placed in DPE.

These reviews concentrate on cases in which problems of compliance surface during DRI's oversight of extramural inquiries and investigations. In addition, investigations of alleged retaliation against whistleblowers are now part of the compliance review process.

Each institutional compliance review contains two major components. The first component compares the institution's policies and procedures with the provisions of the PHS regulation. The process developed by each institution for dealing with allegations of scientific misconduct must incorporate all the specific provisions of the PHS regulation. The institutional policies and procedures are examined for adherence to these specific provisions.

The second component examines the actual administrative process used by the institution in an inquiry and/or investigation of scientific misconduct to determine if the process utilized during that review was consistent with the institution's own policies and procedures and the PHS regulation. Because the current PHS regulation requires that the institutional process include protection of the positions and reputations of those who in good faith make allegations of scientific misconduct, alleged retaliation against whistleblowers also is examined as part of this process.

At the conclusion of each review, a final report is prepared assessing the institution's compliance with both the PHS regulation and the institution's own administrative process. This report is provided to officials at the institution reviewed along with any recommendations for corrective actions.

POLICY AND PROCEDURE DEVELOPMENT

In 1993, ORI focused its policy and procedural efforts on the development of (1) the PHS Research Integrity Program, (2) procedures for handling allegations of scientific misconduct in PHS intramural research programs, and (3) a regulation on the protection of whistleblowers.

PHS Research Integrity Program

Steps were taken by ORI in 1993 to develop administrative structures and processes within each PHS agency for handling allegations of scientific misconduct and promoting research integrity.

These administrative structures and processes span PHS extramural and intramural research programs and perform the following functions: (1) responding to allegations of scientific misconduct in intramural research programs by conducting inquiries and cooperating with ORI investigations; (2) reporting allegations of scientific misconduct received or identified by extramural program officers and scientific review administrators; (3) cooperating with ORI reviews or investigations of extramural allegations; (4) implementing administrative actions imposed on researchers found to have committed scientific misconduct; (5) verifying the eligibility of institutions to receive funding under the PHS Act; and (6) promoting research integrity.

The performance of these functions involves (1) research integrity officers, (2) intramural research directors, (3) extramural research directors, (4) research program officers, (5) scientific review administrators, (6) committee management officers, and (7) grant and contract management officers.

In response to a directive from Dr. Philip R. Lee, Assistant Secretary for Health, each PHS agency head named an Agency Research Integrity Liaison Officer (ARILO) to implement the Research Integrity Program within the Agency. Some agency heads also have named Agency Intramural Research Integrity Officers (AIRIO), Agency Extramural Research Integrity Officers (AERIO), and Research Integrity Officers for components of the agency.

Intramural Procedures for Handling Allegations

A set of updated instructions for handling allegations of scientific misconduct in PHS intramural programs was developed in 1993, similar to those developed for extramural institutions in 1989 (42 C.F.R. Part 50, Subpart A) and was circulated to the PHS ARILOS in 1993.

These instructions for the intramural programs explain that PHS agencies are responsible for conducting inquiries into allegations of misconduct in the PHS intramural program, and that the ORI handles all investigations where inquiries indicate an investigation is warranted. The intramural instructions apply to all instances involving research, research training, or research- related activities for which funds have been provided. They apply to PHS Civil Service and Commissioned Corps employees engaged in research activities, and to other individuals and trainees that conduct research at PHS facilities, including volunteers, guest researchers, and collaborators. The instructions explain the steps and methods that PHS agencies should follow in sequestering records, conducting inquiries, and reporting to ORI.

Regulation on Protection of Whistleblowers

In 1993, development also began on the protection of whistleblowers regulation mandated by the NIH Revitalization Act. The Act requires the Secretary by regulation to establish "standards for preventing and for responding to the occurrence of retaliation by an entity, its officials or agents." This regulation will cover any entity applying for PHS research funds. The regulation will deal with retaliation against an employee who cooperated in an investigation or in good faith made an allegation that the entity, its agent, or officials engaged in or failed to adequately respond to an allegation of scientific misconduct.

EDUCATION AND OUTREACH

In addition to the publication program described in the Significant Accomplishments section, the educational and outreach activities of the ORI staff in 1993 included (1) a conference on plagiarism, (2) a training course, (3) 12 presentations, and (4) two published articles.

Plagiarism Conference

The ORI and the American Association for the Advancement of Science (AAAS) through its Committee on Scientific Freedom and Responsibility and the National Conference of Lawyers and Scientists jointly sponsored a conference, "Plagiarism and the Theft of Ideas" at the NIH on June 21-22, 1993. The conference was attended by 150 scientists and others interested in the issue. Topics included defining the problem in intellectual and historical perspectives, along with a review of the ethical, legal, and policy aspects within a contemporary context. Case studies from university investigations were also reviewed.

Training Course

At the request of the Agricultural Research Service (ARS), U.S. Department of Agriculture, ORI presented a course on July 29, 1993, on investigating scientific misconduct to officials and senior ARS staff responsible for designing and implementing the ARS procedures for responding to allegations of scientific misconduct. Staff from DRI and the Research Integrity Branch, OGC, presented information on legal authorities to investigate; standards of proof; investigational management (such as record-keeping); accepting and clarifying allegations; identifying scientific misconduct issues and referring other issues; securing and handling evidence; notification of parties; and interview and analytical techniques including statistical forensic techniques developed by DRI staff. The instructional techniques included lectures and role-playing of telephone and interviewing techniques.

Presentations

The following 12 presentations were made by ORI staff at meetings, workshops, conferences, universities, and medical schools:

* Bivens, L.W. Panel member for sessions on "The Requirements for Instruction in the Responsible Conduct of Research" and the "Slippery Slope of Data Management - Where Do We Draw the Line between Misconduct and Sloppy Science". Workshop on Educating for the Responsible Conduct of Research: NIH Policy and Other Mandates held by Public Responsibility in Medicine and Research. Boston, MA. April 1-2, 1993.

* Bivens, L.W. "PHS Research Misconduct Policies." Meeting of the National Association of State Universi-

ties and Land Grant Colleges. Washington, D.C. September 20, 1993.

* Bivens, L.W. "Update on the PHS Initiative Regarding Research Misconduct." Society of Research Administrators, 27th Annual Meeting. New Orleans, LA. October 5, 1993.

* Bivens, L.W. "Responsible Conduct in Science." Panel member. Society for Neuroscience. Washington, D.C. November 7, 1993.

* Macfarlane, D.M. "Scientific Misconduct - How the U.S. Public Health Service Handles It." International Conference on Scientific Dishonesty and Good Scientific Practices. Copenhagen, Denmark. November 25, 1993.

* Parrish, D.M. "Current Legal Challenges to the Federal Rules and Regulations Governing Scientific Misconduct." Third Conference on Research Policies and Quality Assurance: Government Regulations. Baltimore, MD. May 4, 1993.

* Price, A.R. "Federal Definitions and Handling of Research Misconduct." University of California, San Diego. Course in Scientific Misconduct. La Jolla, CA. April 8, 1993.

* Price, A.R. "Current Issues in Investigation at the Office of Research Integrity." Panel presentation at Third Conference on Research Policies and Quality Assurance: Government Regulations. Baltimore, MD. May 4, 1993.

* Price, A.R. "Current Controversies in Scientific Integrity and the Role of the ORI." Faculty Colloquium, Michigan State University. East Lansing, MI. September 21, 1993.

* Price, A.R. "Interactions of the ORI and Research Institutions." Faculty Seminar, Medical College of Ohio. Toledo, OH. September 24, 1993.

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Findings of Scientific Misconduct. Vol. 58, p. 33830, June 21, 1993.

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Establishment of Commission on Research Integrity. Vol. 58, p. 66009, December 17, 1993.

OTHER ACTIVITIES

Other ORI activities include (1) maintaining the PHS ALERT System, (2) conducting policy studies, (3) responding to Freedom of Information Act (FOIA) requests, and (4) providing project support.

PHS ALERT System

The PHS ALERT is a system of records under the purview of the Privacy Act. Its primary purpose is to provide relevant information to PHS officials, on a need-to-know basis, about individuals found to have engaged in scientific misconduct. There were 51 names in the system as of December 31, 1993.

The system underwent a significant change in October 1992, when the criteria for entering individual's names into the system were modified. Previously, the names of all individuals accused of scientific misconduct were entered into the system at the initiation of an investigation. Individuals now are entered into the PHS ALERT when: (1) ORI has made a finding of scientific misconduct concerning the individual; (2) the individual is the subject of an administrative action imposed by the Federal government as a result of a determination that scientific misconduct has occurred; (3) the individual has agreed to voluntary corrective action as a result of an investigation of scientific misconduct; (4) ORI has received a report of an investigation by an institution in which there was a finding of scientific misconduct concerning the individual and ORI has determined that PHS has jurisdiction; (5) FDA has determined that there is sufficient reason to believe that official action is warranted against the individual for violation of an FDA regulation governing research.

Policy Studies

In 1993, the ORI contracted with the Research Triangle Institute, Research Triangle Park, NC, to conduct a study of the consequences of whistleblowing for the whistleblower in cases of scientific misconduct. Anecdotal information indicates that some whistleblowers risk their careers by making allegations of misconduct. This project intends to systematically collect information from all known whistleblowers involved in PHS misconduct in science cases to determine what has happened to them since they made their allegations. The study population is to include 100-135 individuals from closed ORI cases. The contractor will collect the data using a self-administered questionnaire. The ORI expects to receive the final study report in February 1995.

Freedom of Information Act Requests

The Freedom of Information Act (FOIA), 5 U.S.C. § 552, provides access to agency records except to the extent that the records are protected from disclosure by one or more of the FOIA's nine exemptions.

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The exemptions which pertain primarily to the ORI records are 5, 6, and 7. Exemption 5 covers internal government communications and notices. Exemption 6 covers documents about individuals that if disclosed the disclosure would constitute a clearly unwarranted invasion of personal privacy. Exemption 7 covers records that the government has compiled for law enforcement purposes.

The first step in processing a FOIA request is for the agency official to determine what records are being sought by the requester. The requester must reasonably describe the records sought so that the agency official is able to locate the record with a reasonable amount of effort. An explanation for the requested information is not necessary.

Ninety requests for ORI documents had been filled in 1993. Of these, 74 were requests for ORI final reports; 2 were for statements of policy and interpretations; 2 were requests for administrative staff manuals and instructions; and 12 were requests for other documents.

Project Support

As part of its commitment to education and outreach, the ORI provided start-up funds for a AAAS project to develop five trigger videos and a documentary on research integrity. The ORI funding enabled the AAAS to begin preparing scripts for two trigger videos. The AAAS has established an advisory committee to ensure that a global representation of science is attained and reflected in the videos. These six videos are intended for use in classes and seminars to stimulate discussion of key issues in research ethics.

APPENDIX

A. List of Tables

Table 1. Disposition of Queries to ORI in 1993
Table 2. ORI Caseload by Case Type During 1993
Table 3. Outcome of Investigations by PHS Research Program, 1993
Table 4. Outcome of Investigations by Institutional Setting, 1993
Table 5. Outcome of Investigations by Funding Mechanism, 1993
Table 6. Outcome of Investigations by Performer of Investigation, 1993
Table 7. Outcome of Investigations by Type of Allegation, 1993
Table 8. Outcome of Investigations by Institutional Action, 1993
Table 9. Frequency of Type of Government Action, 1993
Table 10. Outcome of Investigations by Academic Rank of Respondent, 1993
Table 11. Outcome of Investigations by Highest Academic Degree of Respondent, 1993
Table 12. Outcome of Investigations by Gender of Respondent,1993
Table 13. Outcome of Investigations by Relationship of Complainant to Respondent, 1993
Table 14. Outcome of Investigations by Academic Rank of Complainant, 1993
Table 15. Outcome of Investigations by Highest Academic Degree of Complainant, 1993
Table 16. Outcome of Investigations by Gender of Complainant, 1993
Table 17. Outcome of Investigations by Length of Inquiry, 1993
Table 18. Outcome of Investigations by Length of Investigation, 1993
Table 19. Outcome of Investigations by Size of Inquiry Panel, 1993
Table 20. Outcome of Investigations by Size of the Investigative Panel, 1993

B. Abbreviations

AAAS	American Association for the Advancement of Science
DAB	Departmental Appeals Board
DHHS	Department of Health and Human Services
DPE	Division of Policy and Education, ORI
DRI	Division of Research Investigations, ORI
NIH	National Institutes of Health
ORI	Office of Research Integrity
OSI	Office of Scientific Integrity (ended in 1992)
OSIR	Office of Scientific Integrity Review (ended in 1992)
PHS	Public Health Service
RO1	Research Project (Traditional investigator-initiated grant)
S07	Biomedical Research Support Grant (Research Resources)
UO1	Cooperative Research Project
U10	Cooperative Clinical Research

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